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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,024	09/12/2001	Hua Zhu	03848.00096	1919
28315	7590	07/28/2004	EXAMINER	
BANNER & WITCOFF LTD., ATTORNEYS FOR AFFYMETRIX 1001 G STREET, N.W. ELEVENTH FLOOR WASHINGTON, DC 20001-4597			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 07/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/950,024

**Applicant(s)**

ZHU ET AL.

**Examiner**

Young J. Kim

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-23 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-23 and 30-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action responds the Amendment received on May 12, 2004.

#### ***Preliminary Remark***

The Office acknowledges the cancellation of claims 46 and 47, drawn to non-elected invention, non-elected without traverse in the Election received on October 22, 2003.

The Office acknowledges the cancellation of claims 4 and 24-29.

Applicants indicate that claims 25-29 have been canceled in their "Response/Argument" section (page 11, 5<sup>th</sup> paragraph). However, the actual amendment to the claims cancels claims 24 through 29. It appears that the statement made in the "Response/Argument" section is a typographical error. Applicants are requested to clarify in their response.

#### ***Claim Objections - Withdrawn***

The objection of claim 4 being drawn to non-elected invention, made in the Office Action mailed on January 15, 2004, is withdrawn in view of the Amendment received on May 12, 2004, canceling the claim.

The objection of claims 11 and 13 for containing minor typographical errors, made in the Office Action mailed on January 15, 2004, is withdrawn in view of the Amendment received on May 12, 2004.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1, 2, and 4-45 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on January 15, 2004 is withdrawn in view of the Amendment received on May 12, 2004.

***Rejection – Necessitated by Amendment***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-23, and 30-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 and their dependent claims 5-23 and 30-43 are indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Elrich*, 3 USPQ2d, p. 1011 (Bd. Pat App. Int. 1986). For example, the independent claims are drawn to a method of determining the stage of disease caused by HCMV infection (claim 1); a method of determining the extent of tissue damage caused by HCMV infection (claim 2); and a method of screening to identify candidate drugs for preventing disease symptoms caused by HCMV (claim 3), yet the claims only recite the step of determining the expression level in a first human cell sample for a set of recited genes. The claims do not set forth the conditions/state when the method has been completed [i.e., needs to agree with preamble].

Claim 1-3 and their dependent claims 5-23 and 30-45 are indefinite because the independent claims 1-3 recite the phrases: a) “wherein the first human cell sample comprises cells of a patient infected with HCMV” and b) “wherein the first human cell sample consists essentially of HCMV-infected cells.” It is unclear whether the first human cell sample is *either* a) or b); or a) **and** b). For the purpose of prosecution, the former interpretation is assumed.

Art Unit: 1637

Claims 5-9 are indefinite for the recitation of the phrase, “wherein one or more of the set of genes are induced or repressed.” Claims are indefinite in whether the phrase should be interpreted as “one or more genes from the set identified in the independent claims 1-3”; or one or more set (of genes) identified in the independent claims 1-3. If the latter interpretation is assumed, the claims would lack proper antecedent basis since claims 5-9 depend on independent claims 1-3, which only recite *a single set* of genes. .

Claims 18-23 are indefinite for being drawn to non-elected invention. Applicants are reminded that the claims of the instant application had been amended to recite a method involving a specific set of genes, the set of genes which were elected without traverse in the Election received on October 22, 2003. The genes identified in claims 18-23, however, were not part of the elected gene set nor recited in claims 1-3. Therefore, claims lack proper antecedent basis **as well as being drawn to non-elected invention**. Additionally, the claims are indefinite because it is unclear whether the phrase, “in which the set of genes comprise (*sic*),” is meant to indicate that the set of genes need essentially comprise, for example, HLA-E gene; **or the set of genes** (recited in independent claims 1-3) **further comprises** HLA-E gene.

Claims 30-36 are also indefinite because it is unclear whether the number of genes involved in the expression level determination is selected from the set of genes recited in independent claims 1-3 or *any genes*. The indefiniteness arises because the number of genes required in claims 30-36 **exceeds** the number of genes recited in the set of genes in claims 1-3.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

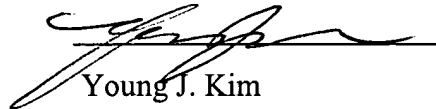
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). **NOTE:** If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office. All official

Art Unit: 1637

documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Young J. Kim  
Patent Examiner  
Art Unit 1637  
7/19/04

yjk



KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

7/22/04